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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,160	03/31/2004	Suman Preet Singh Khanuja	Q80746	4467
23373	7590	08/10/2007		
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER GOLDBERG, JEANINE ANNE	
			ART UNIT 1634	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/813,160

Applicant(s)

KHANUJA ET AL.

Examiner

Jeanine A. Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 8/07
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed 3/31/2004. Currently, claims 1-9 are pending. Claims 3-9 are withdrawn from consideration.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Election/Restrictions

4. Applicant's election of Group I in the reply filed on 11/13/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/2006.

Priority

5. This application is a continuation of PCT/IN03/00404 filed 11/29/2003.

Claim Rejections - 35 USC § 112-Description

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure.

The instant claims encompass a large genus of nucleic acids directed to any pair of primers "having" sequence of SEQ ID No.1 and 2. The current claims encompass any set of primers comprising, a) a primer with a sequence of SEQ ID No 1, including primers with extensions on 5' and /or 3' ends of SEQ ID NO:1; b) a primer with a sequence of SEQ ID No 2, including primers with extensions on 5' and /or 3' of SEQ ID 2. The extensions can be any number one and above. Because claim 1 recites "having sequence of", a primer consisting of the sequence 5'-

ACCAAGCTTGCTGAACGCATCGGAAAAAAAAA-3', for example, is a primer having SEQ ID NO.1 sequence, underlined, but with one A at its 5' and 10 A's at its 3'ends.

With regard to claim 2, the instant claim is directed to any primer set "having" SEQ ID NOs: 1 and 2 sequences that help identify plants Artemisia annua containing high content of artemisinin. Therefore the claims encompasses any nucleotides on

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either side of the recited primer sequences. However, the specification does not teach the large number of potential primer sets encompassed by the broad claim language as discussed above. It is noted that the specification teaches SEQ ID NO:3, which is the PCR product sequence amplified with SEQ ID NOs: 1 and 2 as primers. However, the specification does not teach which additional sequences on either side of the recited primers other than the sequences within SEQ ID NO: 3, which would amplify and help identify plants with high artemisinin contents.

The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. One of skill in the art would conclude that applicant was not in possession of the claimed genus because no description of any class of this genus is disclosed to support the claims.

The instant claims do not meet the written description provision of 35 USC 112, First Paragraph. Applicants are reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 1115).

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43. USPQ2b 1398-1412), the court held that a generic statement which defines a genus of

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nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B (1), the court states that "An adequate written description of a DNA. . .' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention.

Conclusion

The applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus on a large region of human chromosome.

Response to Arguments

The response traverses the rejection. The response asserts that Vas-Cath is factually inapposite here as the catheter designs comprising a pair of tubes (lumens). This argument has been considered but is not convincing because the principles behind Written Description, regardless of the subject matter, may be inferred from Vas-Cath.

The response asserts that the claims are not read in isolation but rather in view of the specification. The response asserts that one skilled in the art would appreciate that the instant claims do not encompass a genus of nucleic acids directed to any pair of

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primers having SE QID NO: 1 and 2. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Having is a broad recitation, much like comprising which broadly read to encompass any primer minimally having SEQ ID NO: 1 and 2. While the response asserts that the claims do not read on any pair of primers of SEQ ID NO: 1 and 2, the plain language of the claims encompasses any pair of primers minimally comprising SEQ ID NO: 1 and 2. Since the record appears to assert that the claims do not encompass a genus of nucleic acids directed to ANY pair of primers having SEQ ID NO: 1 and 2, it is unclear which members of the genus are excluded from the claims.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the

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court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention and breadth of claims

The instant claims encompass a set of primers having SEQ ID NOs: 1 and 2 sequences, including primers that have extensions on 5' and /or 3' ends of SEQ ID NOs:1 and 2. With regard to claim 2, the claim is directed to any primer set "having" SEQ ID NOs: 1 and 2 that help identify plants *Artemisia annua* containing high content of artemisinin. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

The art does not teach how to make a set of primers having SEQ ID NOs: 1 and 2 sequences with additional features such as various extensions to the ends of the primers which would amplify and help identify plants with high artemisinin contents.

Guidance in the Specification.

The specification disclosed the use of primers consisting of SEQ ID NOs: 1 and 2 as forward and reverse primers in PCR reactions. The specification does not teach any

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other primers encompassed by the instant claims such as primers with extensions on either side of SEQ ID NOs. 1 and 2 primers as explained above. With regard to claim 2, the instant claim is directed to any primer set "having" SEQ ID NOs: 1 and 2 sequences that help identify plants Artemisia annua containing high content of artemisinin.

Therefore the claims encompasses any nucleotides on either side of the recited primer sequences. However, the specification does not teach the large number of potential primer sets encompassed by the broad claim language as discussed above. It is noted that the specification teaches SEQ ID NO:3, which is the PCR product sequence amplified with SEQ ID NOs: 1 and 2 as primers. However, the specification does not teach which additional sequences on either side of the recited primers other than the sequences within SEQ ID NO: 3 that would amplify and help identify plants with high artemisinin contents.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention.

Working Examples

The specification has no working example of primers other than the sequences of SEQ ID NOs: 1 and 2.

Quantity of Experimentation

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The quantity of experimentation in this area is extremely large since there is significant number of parameters, which would have to be studied such as all combination of SEQ ID NOs:1 and 2 sub-sequences and sequences with 5' and 3' extensions.

This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the genus of primers having sequences of SEQ ID NOs: 1 and 2 is very large, the specification teaches no additional examples of primers, other than sequences of the SEQ ID NOs: 1 and 2, which would function to help identify plants Artemisia annua containing high content of artemisinin.

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

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The response traverses the rejection. The response asserts that the sequences have been clearly described and one could practice the claims without undue experimentation. This argument has been considered but is not convincing because the large genus claimed does not clearly illustrate which primers may be used for the intended use of Claim 1.

The examiner notes that the disclosure sets forth particular examples using primers consisting of SEQ ID NO: 1 and 2. As noted above in the response to arguments, limitations from the specification are not read into the claims. Thus, the detailed analysis provided does not further limit the claimed invention.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

7. No claims allowable.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.


Jeanine Goldberg
Primary Examiner
August 6, 2007